



Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and or lordosis), tumor, stenosis, pseudoarthrosis, and failed previous fusion. The transverse connector is not intended for anterior/anterolateral fixation.

6. **Materials:** The components of the System are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136.
7. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between the EBI<sup>®</sup> SpineLink<sup>®</sup> - II Spinal Fixation System and other legally marketed spinal systems. It is substantially equivalent\* to the predicate devices in regards to intended use, materials, and function. Mechanical testing comparing the System to predicate systems demonstrates that the device complies with applicable standards and meets all of its functional requirements.

\*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 22 2003

Mr. Jon Caparotta, RAC  
Manager, Regulatory Affairs  
EBI, L.P.  
100 Interpace Parkway  
Parsippany, New Jersey 07054

Re: K031355  
Trade Name: EBI® SpineLink™ II Spinal Fixation System  
Regulation Number: 21 CFR 888.3070, 888.3060, 888.3050  
Regulation Name: Pedicle screw spinal system, Spinal intervertebral body fixation  
orthosis, Spinal interlaminar fixation orthosis  
Regulatory Class: III  
Product Code: NKB, MNI, MNH, KWQ, KWP  
Dated: April 28, 2003  
Received: April 30, 2003

Dear Mr. Caparotta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

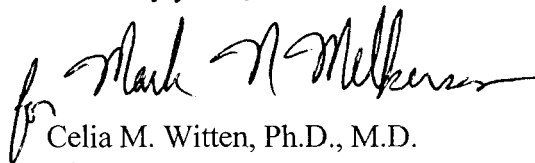
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Statement of Indications for Use**

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510(k) Number (if known): K031355

Device Name: EBI® SpineLink® - II Spinal Fixation System

**Indications For Use:**

The EBI® SpineLink® II Spinal Fixation System is a non-cervical spinal fixation device intended for use as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and or lordosis), tumor, stenosis, pseudoarthrosis, and failed previous fusion. The transverse connector is not intended for anterior/anterolateral fixation.

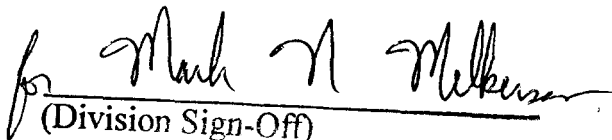
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\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use  
(Optional Format 1-2-96)

  
(Division Sign-Off)

Division of General, Restorative  
and Neurological Devices

510(k) Number K031355